

UNITED STATES DISTRICT COURT
DISTRICT OF NEW JERSEY

SOUTHERN RESEARCH INSTITUTE and
GENZYME CORPORATION,

Plaintiffs,

v.

ABON PHARMACEUTICALS LLC,

Defendant.

HONORABLE JOSEPH E. IRENAS

CIVIL ACTION NO. 12-04709
(JEI/KMW)

OPINION

APPEARANCES:

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IRENAS, Senior District Judge:

This patent infringement suit comes before the Court on
Plaintiffs Southern Research Institute ("SRI") and Genzyme
Corporation's ("Genzyme") motion for leave to file a Second

Amended Complaint.¹ (Dkt. No. 80) Defendant Abon Pharmaceuticals LLC ("Abon") subsequently cross-moved to dismiss Plaintiffs' First Amended Complaint (Dkt. No. 88), in which Plaintiffs allege Abon infringed U.S. Patent No. 5,661,136 (the "'136 patent"), which SRI holds, by filing an Abbreviated New Drug Application ("ANDA") for FDA approval of a generic version of Clolar®, a drug used for the treatment of pediatric patients with lymphoblastic leukemia.² (Am. Compl. ¶ 15)

Plaintiffs seek to join as a plaintiff Sanofi-Aventis U.S. LLC ("Sanofi"), the exclusive sublicensee of Clolar®. Genzyme and Sanofi executed the sublicense "after Plaintiffs [completed] their pre-filing investigation of ownership of the patents," (Pls.' Ltr Br. at 2), and consequently Plaintiffs did not learn of Sanofi's relevance to the instant dispute until "late 2013," one and a half years after the suit was filed. (Opp'n Br. at 4)

Abon argues that in light of the exclusive sublicense, Plaintiffs lack standing without Sanofi and consequently Plaintiffs' complaint should be dismissed, not amended. Abon further argues that because Plaintiffs did not reveal Sanofi's role until a year and a half after filing suit, Plaintiffs' suit should be dismissed with prejudice. Abon so moves because a

¹ The Court has subject matter jurisdiction pursuant to 28 U.S.C. §§ 1331 and 1338(a).

² Abon notified Plaintiffs of the application in a letter dated June 14, 2012. (Am. Compl. ¶ 9)

dismissal would terminate the 30-month stay currently freezing Abon's ANDA. See 21 U.S.C. § 355(j)(5)(B)(iii).

As detailed below, the Court holds that Plaintiffs have standing to sue, and consequently will deny Abon's cross-motion to dismiss. Plaintiffs' motion for leave to add Sanofi as a plaintiff will be granted.

I.

The '136 patent was issued on August 26, 1997 to John A. Montgomery and John A. Secrist, III and assigned to SRI. (Am. Compl. ¶ 8) The patent will expire on January 14, 2018. (Id.)

On October 1, 2010, SRI granted Genzyme, through their Amended and Restated Co-Development Agreement ("Co-Development Agreement"), "the exclusive right to make, have made, use, and sell Products that otherwise would infringe, inter alia, the '136 patent, [] for use in the human health applications." (Opp'n Br. at 5-6) The grant extends throughout the "entire world excluding Southeast Asia," (Co-Development Agreement § 1(W)), and lasts "for so long as Genzyme meets the [Agreement's] payments and other obligations[.]" (Id. § 2(B))

With regards to an infringement prosecution, the Co-Development Agreement grants Genzyme "the first right, but not the obligation, to institute and direct suit for infringement(s) . . . of the Patents in the Field and Territory through its own

counsel and at its own expense so long as this Agreement remains exclusive." (Co-Development Agreement §10(B)) "If SRI notifies Genzyme of its desire to institute and direct suit for infringement(s) . . . and Genzyme does not exercise its first right to do so . . . then SRI may, at its own expense and upon consultation with Genzyme, bring suit or take any other appropriate action." (Id.)

On June 14, 2012, Abon notified Plaintiffs of its ANDA.
(Am. Compl. ¶ 9)

On July 1, 2012, Genzyme and Sanofi entered into a License and Supply Agreement in which Genzyme granted Sanofi "an exclusive, non-transferable license, together with the right to grant sublicenses . . . [to] make, have made, import, market, distribute, use, offer to sell, and sell" the drug Clolar®.³
(License and Supply Agreement § 2.1, Schedule 1) Genzyme and Sanofi are both "in the Sanofi group of companies." (Pls.' Ltr Br. at 2)

As to infringement prosecution, Sanofi "shall have the right to institute an action based on such infringement or threatened infringement and shall be responsible for the conduct and cost of such action. Genzyme shall provide to Sanofi all

³ The License and Supply Agreement granted Sanofi such rights in connection with five drugs: Campath, Celsior, Mozobil, Thymoglobulin, and Clolar®.
(License and Supply Agreement § 2.1, Schedule 1)

assistance reasonably required by Sanofi to engage and pursue such proceedings to a satisfactory conclusion." (License and Supply Agreement § 10.1) The agreement does not specify whether Genzyme retains an independent right to bring claims of infringement, although it does reserve for Genzyme "any right, title or interest" in the patent not expressly granted to Sanofi. (Id. § 2.3)

On July 27, 2012, Plaintiffs filed their original complaint. (Dkt. No. 1) Sanofi was not a party to the litigation.

On October 4, 2012, Plaintiffs filed their First Amended Complaint, wherein they removed allegations of willful infringement. (Dkt. No. 20) Plaintiffs again did not include Sanofi.

Abon filed an Amended Answer and counterclaims on October 15, 2012, denying any infringement and seeking a declaratory judgment stating the patent is invalid and not infringed. (Dkt. No. 22)

On October 11, 2012, Magistrate Judge Williams entered a Scheduling Order setting May 17, 2013 as the deadline for seeking amendments to the pleadings. (Dkt. No. 23) No amendments were made within the allotted time.

The Court held a Markman hearing August 13, 2013 and issued an opinion and order on the disputed terms August 22, 2013. (Dkt. Nos. 60, 61)

In "late 2013," Plaintiffs "became aware of a revenue sharing arrangement between Genzyme and Sanofi in the context of another, unrelated litigation." (Pls.' Ltr Br. at 2) Plaintiffs subsequently obtained the sublicense and produced it to Abon.

On December 3, 2013, Plaintiffs sought Abon's consent to add Sanofi as a plaintiff. (Pls.' Ltr Br. at 3) With Abon's consent not forthcoming, Plaintiffs filed the instant motion for leave on December 13, 2013. (Dkt. No. 80) At the time, December 13, 2013 was the end of fact discovery. Judge Williams subsequently extended the deadline to January 31, 2014.⁴

Defendant cross-moved to dismiss December 23, 2013. (Dkt. No. 88)

⁴ The end of fact discovery was originally November 1, 2013. However, in an October 15, 2013 letter to Judge Williams, Plaintiffs wrote that in "working with [their] third-party document production vendor," they had found a "significant" amount of responsive documents remaining, and consequently sought, with Abon's consent, adjournment of the deadline. The letter was also sent because the parties were to have "substantial[ly] complet[ed]" document production by August 14, 2013, and Plaintiffs, upon finding the responsive documents, realized they had missed the deadline.

II.

Federal Rule of Civil Procedure 15(a)(2) controls motions to amend and holds that “[t]he court should freely give leave [to amend] when justice so requires.” See also Fed. R. Civ. P. 21 (“Misjoinder of parties is not a ground for dismissing an action. On motion or on its own, the court may at any time, on just terms, add or drop a party. The court may also sever any claim against a party.”).

The Court “may only deny leave to amend in two circumstances: (1) if a plaintiff’s delay in seeking amendment is undue, motivated by bad faith, or prejudicial to the defendant; or (2) if the amendment would be futile.” Paladino v. Newsom, Civ. No. 12-2021, 2014 WL 70069, at *1 (D.N.J. Jan. 9, 2014) (internal quotations omitted).

A party seeking to amend in contravention of a court’s scheduling order can only do so “for good cause and with the judge’s consent.” Fed. R. Civ. P. 16(b)(4).

Federal Rule of Civil of Procedure 12(b)(1) provides that a party may bring a motion to dismiss for lack of subject matter jurisdiction, including a lack of standing. Ballentine v. United States, 486 F.3d 806, 810 (3d Cir. 2007). The party invoking federal jurisdiction bears the burden of establishing the elements of standing. Focus v. Allegheny Cnty. Court of Common Pleas, 75 F.3d 834, 848 (3d Cir. 1996). When the

challenging party presents a factual challenge, the trial court is free to weigh the evidence and satisfy itself as to the existence of its power to hear the case. Petruska v. Gannon Univ., 462 F.3d 294, 302 n. 3 (3d Cir. 2006).

III.

The Court first addresses Abon's cross-motion to dismiss and then Plaintiffs' motion for leave to amend.

A.

Because SRI and Genzyme have standing to sue, Abon's motion to dismiss will be denied. Cf. Schreiber Foods, Inc. v. Beatrice Cheese, Inc., 402 F.3d 1198, 1203 (2005) ("In the area of patent infringement . . . if the original plaintiff lacked Article III initial standing, the suit must be dismissed, and the jurisdictional defect cannot be cured by the addition of a party with standing."). The Court addresses the standing of each Plaintiff in turn.

1.

Patent holders, in their own right, usually have standing to prosecute claims of infringement. Such standing is only lost if the patent holder "grant[s] an exclusive license to [its] patent[]" under such terms that the license is tantamount to an

assignment of the patent[] to the exclusive licensee. This happens when the exclusive license transfers all substantial rights in the patent[]." Alfred E. Mann v. Cochlear Corp., 604 F.3d 1354, 1359 (Fed. Cir. 2010).

SRI did not transfer to Genzyme all substantial rights in the '136 patent.

When determining whether all substantial rights have been transferred, the Federal Circuit looks at the scope of the license in relation to the "bundle of rights" that make up a patent. Alfred E. Mann, 604 F.3d at 1360; Vaupel Textilmaschinen KG v. Meccanica Euro Italia SPA, 944 F.2d 870, 874 (Fed. Cir. 1991) ("In determining whether a provision in a contract constitutes an assignment or a license, the court must look to the parties' intent and examine the substance of what was granted.").

Necessary for an assignment, but insufficient in itself, "is the transfer of the exclusive right to make, use and sell products or services under the patent." Propat Int'l Corp. v. R. Post, Inc., 473 F.3d 1187, 1193-94 (Fed. Cir. 2007). Other factors the Circuit examines are

the scope of the licensee's right to sublicense, the nature of license provisions regarding the reversion of rights to the licensor following breaches of the license agreement, the right of the licensor to receive a portion of the recovery in infringement suits brought by the licensee, the duration of the license rights granted to the licensee, the ability of the licensor to supervise

and control the licensee's activities, the obligation of the licensor to continue paying patent maintenance fees, and the nature of any limits on the licensee's right to assign its interests in the patent.

Alfred E. Mann, 604 F.3d at 1360-61.⁵

Two rules have emerged from this multi-factor analysis that indicate SRI's transfer was not an assignment.

First, where the licensor retains a right to sue accused infringers, and the licensee lacks the ability to moot licensor-initiated litigation by granting royalty-free sublicenses to the accused infringer, the licensor does not transfer all substantial rights. Alfred E. Mann, 604 F.3d at 1361; Speedplay, Inc. v. Bebo, Inc., 211 F.3d 1245, 1251 (Fed. Cir. 2000).

Second, field of use licenses do not constitute a transfer of all substantial rights in the patent. Pope Mfg. Co. v. Gormully & Jeffery Mfg. Co., 144 U.S. 248 (1892) (holding that a plaintiff with exclusive rights limited to a particular embodiment of the claimed invention did not have standing to sue in his own name); Int'l Gamco, Inc. v. Multimedia Games, Inc., 504 F.3d 1273, 1280 (Fed. Cir. 2007) ("[A]n exclusive enterprise

⁵ See also Alfred E. Mann, 604 F.3d at 1361 ("Under the prior decisions of this court, the nature and scope of the licensor's retained right to sue accused infringers is the most important factor in determining whether an exclusive license transfers sufficient rights to render the licensee the owner of the patent.")

licensee [] does not hold all substantial rights in the full scope of the [] patent.").⁶

Both rules indicate that SRI did not transfer all substantial rights in the '136 patent.

First, SRI retains a right to sue accused infringers and Genzyme lacks the ability to moot SRI's suits. The Co-Development Agreement specifies that for any claim of infringement Genzyme does not pursue, "SRI may, at its own expense and upon consultation with Genzyme, bring suit or take any other appropriate action." (Co-Development Agreement §10(B))

Further, the Agreement precludes Genzyme from interfering with this right by granting a non-royalty bearing sublicense. (Co-Development Agreement § 5(B) ("SRI shall have the right to review the form of sublicenses to be granted hereunder prior to the execution of the same. . . . Genzyme agrees that [any] sublicense agreement shall confirm in all material respects to the terms and conditions of this Agreement. . . . If SRI has not objected within thirty days of receiving the [sublicense's]

⁶ Perhaps surprisingly, a license can constitute an assignment even if the licensee's rights are limited geographically. See 35 U.S.C. § 261 ("The applicant, patentee, or his assigns or legal representatives may in like manner grant and convey an exclusive right under his application for patent, or patents, to the whole or any specified part of the United States."); Int'l Gamco, Inc. v. Multimedia Games, Inc., 504 F.3d 1273, 1276 (Fed. Cir. 2007) ("The Supreme Court has confirmed that exclusive territorial licensees need not join the licensor to maintain a suit for patent infringement.") (citing Waterman v. Mackenzie, 138 U.S. 252, 255 (1891)).

material terms, Genzyme or its Affiliates may proceed to negotiate and grant sublicenses without further review"); §4(A) - 4(D) (setting forth the financial terms of the agreement that must be adhered to for any product produced that would infringe the patent but for the license)).

Second, the Co-Development Agreement clearly indicates that Genzyme is a field of use licensee. Section 2(A) states "SRI hereby grants to Genzyme and its Affiliates, to the extent of the Field for the Territory, an exclusive license to make, have made, use and sell Products," with "Field" meaning "the practice of the Patent, Invention and Technical Information licensed hereunder for use in human health applications." (Co-Development Agreement §1(F)) Such language clearly shows that SRI only licensed a limited universe of its rights in the '136 patent—those with an application to human health.

Consequently, SRI did not transfer all substantial rights to Genzyme and SRI thereby retained standing to sue infringers of the '136 patent.

2.

Because Genzyme is an exclusive licensee with less than all substantial rights in the '136 patent, and because it did not assign all of its rights to Sanofi, Genzyme has standing to sue Abon.

The Federal Circuit's "prudential standing requirement compels an exclusive licensee with less than all substantial rights, such as a field of use licensee, to join the patentee before initiating suit." Int'l Gamco, Inc., 504 F.3d at 1278. As indicated supra, Genzyme is a field of use licensee with less than all substantial rights. Consequently, Genzyme and SRI were both properly joined as plaintiffs from the suit's outset.

Additionally, Genzyme did not assign all of its rights in its field of use to Sanofi. Rather, the License and Supply Agreement granted Sanofi only "an exclusive, non-transferable license, together with the right to grant sublicenses . . . [to] make, have made, import, market, distribute, use, offer to sell, and sell" the drug Clolar®. (License and Supply Agreement § 2.1, Schedule 1) This limited grant means that Genzyme retains interest in any possible infringement of the patent within the field of human health by a drug other than Clolar®, or an imitation thereof, and consequently has standing to sue Abon.

In light of the fact both SRI and Genzyme have standing to sue Abon, Abon's motion to dismiss will be denied.

B.

Although the Court is surprised by Plaintiffs' unexplained failure to inform themselves or Abon of the sublicense for one

and a half years, Plaintiffs' motion for leave to add Sanofi as a plaintiff will be granted.

Abon itself admits that Sanofi has a relevant interest in the '136 patent, and the Federal Circuit is clear that courts should include authorized parties in infringement suits to prevent multiple suits stemming from a single act of infringement. See Al23 Systems, Inc. v Hydro-Quebec, 626 F.3d 1213, 1222 (Fed. Cir. 2010); Int'l Gamco, Inc., 504 F.3d at 1278.

Furthermore, although Sanofi's addition may cause additional legal work for Abon, it is not prejudicial. If Abon requires further discovery because of Sanofi's inclusion, it can seek such relief from the Court.

Consequently, Plaintiffs' motion for leave to add Sanofi as a plaintiff will be granted.

IV.

Abon also moves to seal the License and Supply Agreement entered into between Genzyme and Sanofi, marked as Exhibit B to Abon's December 23, 2013 brief. (Dkt. No. 90) Upon production, Plaintiffs marked the sublicense "Highly Confidential" under the Court's Discovery Confidentiality Order ("Discovery Order"), and pursuant to that order, Abon filed the agreement, and those portions of its brief that reference the agreement, under seal.

Pursuant to the Discovery Order, the Court will grant the motion.

v.

For the reasons stated above, Abon's motion to dismiss Plaintiffs' First Amended Complaint will be denied. Plaintiffs' motion for leave to amend will be granted. Abon's motion to seal Exhibit B to its December 23, 2013 brief will be granted. An appropriate order accompanies this opinion.

Date: February _4_, 2014

____/s/ Joseph E. Irenas_____

Hon. Joseph E. Irenas
Senior United States District Judge